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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,203	09/18/2003	Rong Wen	MACUS.002A	5747

20995 7590 08/04/2010

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EXAMINER	
FAY, ZOHREH A	

ART UNIT	PAPER NUMBER
1612	

NOTIFICATION DATE	DELIVERY MODE
08/04/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/665,203	WEN ET AL.	
	Examiner	Art Unit	
	ZOHREH A. FAY	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 May 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *30-34,37-39,41-48,50-56 and 63-74* is/are pending in the application.

4a) Of the above claim(s) *75,122,125,127-130,132 and 134* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30-34,37-39,42-48,50-56 and 63-74* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/2/2009, 7/23/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claims 30-34, 37-39, 41-48, 50-56, 63-75, 122-125, 127-130, 132 and 134 are pending in the instant application.

Claims 75, 122-125, 125, 127-130, 132 and 134 are withdrawn from examination.

Claims 30-34, 37-39, 41-48, 50-56, 63-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mollison (US 6,015,815) in view of Kulkami (US 5,387,589) and further over Hu et al. (US 5,800,807) for the reasons set forth on pages 3-5 of the office action of January 12, 2010 and page 2 of the office action of November 18, 2010.

Applicant's arguments and declaration have been carefully considered. Applicant in his remarks argues that none of the references teach the use of a macromolecule in combination with polyethylene glycol for ophthalmic use administered by injection. It is the examiner's position that Mollison teaches the addition of polyethylene glycol to rapamycin. Mollison in column 12 teaches ethanol, polyols such as, glycerol, polyethylene glycol and propylene glycol as carriers for rapamycin. Such teaching indicates polyethylene glycol and propylene glycol are equally suitable as carriers for rapamycin. Kulkami teaches the intravitreal administration for rapamycin as old and well known. Applicant has selected a well known carrier for ophthalmic formulations and has used it by intravitreal administration in order to overcome the disadvantages of using polyethylene glycol. However, there is no evidence of record to demonstrate the advantages of using poly ethylene glycol, a compound not suitable for ophthalmic administration as argued by the applicant over other carriers such as glycerin and propylene glycol. In conclusion: the prior art teaches the use of rapamycin in combination with propylene glycol, polyethylene glycol and glycerin. The prior art

also teaches that rapamycin has been previously used in ophthalmic formulation by intravitreal administration. Applicant has picked a well known ophthalmic carrier such as, polyethylene glycol and uses it with rapamycin which has been previously used by intravitreal administration. It would ha been obvious to a person skilled in the art to use rapamycin by intravitreal administration, considering that Kulkami teaches the use of rapamycin in combination with ophthalmic acceptable carrier by intravitreal administration. The addition of polyethylene glycol to rapamycin and use it by injection does not create a patentably distinct composition.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ZOHREH A. FAY whose telephone number is (571)272-0573. The examiner can normally be reached on Monday to Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fredrick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ZF
/Zohreh A Fay/
Primary Examiner, Art Unit 1612